UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

7590 09/15/2006

Scott D. Rothenberger
DORSEY & WHITNEY LLP
Intellectual Property Department
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498

EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,268	FANTUZZI, MICHAEL	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15,18-20,22,23,32-43 and 45-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,18-20,22,23,32-43 and 45-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 31, 2006 has been entered.

No claims have been amended, canceled or added. Accordingly, claims 14, 15, 18-20, 22, 23, 32-43 and 45-51 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

As previously discussed, claim 35 is objected to under 37 CFR 1.75 as being an exact duplicate of claim 34. This claim was canceled by examiner's amendment on August 26, 2005, although it reappears in the instant RCE. A claim that has been canceled may not be added back in with the same claim number. It may, however, be added as a new claim with a new claim number. But, an application may not contain duplicate claims.

Claim Rejections - 35 USC § 103

Claims 14, 15, 18-20, 22, 23, 32-43 and 45-51 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Erwin (US 2005/0025756) in view of Soft Gel Technologies,

Inc. (EP 888774) and Davidson et al. (US 2004/0001874). This rejection was discussed in the previous Office actions.

Applicant asserts that the claimed invention is not obvious because Erwin does not suggest encapsulating his coQ 10 (coenzyme Q-10) solution in a soft gel capsule, and Soft Gel does not teach or suggest that rice bran oil or vitamin E dissolves coQ 10. Applicant also asserts that Soft Gel does not teach or suggest using a monoterpene such as limonene as a carrier for any ingredient. Further, Applicant asserts that limonene, vitamin E and rice bran oil are three different solvents and that there is no teaching, suggestion, expectation of success or motivation that these solvents may be used interchangeably. Applicant asserts that Davidson et al. disclose soft gels containing coQ 10 in fish oil, but the reference does not state that the fish oil dissolves the coQ 10, and the reference does not suggest substituting limonene for fish oil.

In reply, Erwin discloses that coQ 10 is soluble in limonene, as well as in a number of lipophilic solvents, which are various plant oils, fatty acids and fatty acid esters, including the ester form of vitamin E, tocopheroyl acetate (see paragraphs 40 and 42). Dissolving coQ 10 in one or more of these solvents improves the absorption efficacy and uptake by the body and helps maintain coQ 10 in the reduced state (see paragraph 33). These solvents differ in their chemical structures and chemical properties, but the teachings of Erwin provide the expectation that one could dissolve coQ 10 in a solvent that is a lipid or that is hydrophobic. It is clear in the previous Office actions that Erwin was not cited for teachings related to soft gels.

Soft Gel discloses soft gels containing coQ 10 in rice bran oil or vitamin E. Soft Gel also discloses that its formulations are an improvement over those of Folkers et al. (US 4,824,669), who disclose soft gels containing coQ 10 dissolved in soybean oil, another plant oil. Soft Gel does not state explicitly that the coQ 10 is dissolved in the rice bran oil or vitamin E. But, Soft Gel also does not state explicitly that the coQ 10 is suspended in the rice bran oil or vitamin E,

contrary to Applicant's comment on p. 7 of his response. If a suspension were adequate for formulating soft gels, one of ordinary skill in the art would have used water or a buffered aqueous solution, which would have been significantly cheaper than rice bran oil or vitamin E. As previously discussed, the reference certainly implies that the coQ 10 was dissolved in one of these oils, because, at the time of Soft Gel, coQ 10 was known to be soluble in plant oils. If the coQ 10 were not soluble in the rice bran oil, a precipitate would form, or a two-phase solution would form. In that event, the liquid- the rice bran oil- could not have been manipulated to produce uniform soft gel capsules for dose control, each containing the same amount of coQ 10 and the same amount of rice bran oil, which provides the improved intestinal absorption compared to dry formulations (see p. 2, lines 31-52, and p. 3, lines 4-6). Although the two solvents, limonene and rice bran oil, have different chemical structures, both can be used to prepare solutions of coQ 10. Thus, they may be used interchangeably. It is prima facie obvious to dissolve a compound in a solvent in which the compound is known to be soluble and to use a liquid vehicle for that compound which has been shown to be successful in formulating that compound. For interchangeability, it does not matter that the two solvents have different chemical structures and properties. What matters is that coQ 10 is soluble in both of them.

Regarding the solubility of coQ 10 in vitamin E, the instant claims do not recite that coQ 10 is dissolved in vitamin E or in an antioxidant. The claims recite merely that an antioxidant or a tocopherol is a further component of the soft gel capsules (claims 20 and 51). As discussed previously, Soft Gel discloses the addition of vitamin E as a further component of its soft gel capsules (see p. 2, lines 49-52, and p. 3, lines 4-6).

Similarly, as previously discussed, regarding the solubility of coQ 10 in fish oil, the instant claims do not recite that coQ 10 is dissolved in fish oil. The claims recite merely that fish oil is a further component of the soft gel capsules (claims 40 and 50). As discussed previously,

Davidson et al. disclose that coQ 10 may be blended with fish oil and that this liquid composition may be formulated as a soft gel capsule (see paragraphs 54 and 57). As with Soft Gel, Davidson et al. do not use the words "dissolved" or "solubilized." But, because coQ 10 is miscible with fish oil, the reference implies that the coQ 10 is soluble in the fish oil. Otherwise, as in the case of Soft Gel, this liquid- the fish oil- could not have been manipulated to produce uniform soft gel capsules for dose control, each containing the same amount of coQ 10 and the same amount of fish oil.

Regarding formulating coQ 10 in a soft gel capsule, soft gels were a routine formulation, standard in the art of formulating nutraceuticals and pharmaceuticals at the time of Applicants invention. Thus, at the time of Applicant's invention, it would have been routine to formulate a liquid containing a therapeutically effective dose of any agent as a soft gel. Soft gels have the advantages of oral formulations (they may be self-administered, without the complications of injection or intravenous administration), without the need for measuring out the dose to be administered, as with liquids. Also, soft gels are more comfortable to swallow than hard pills or capsules, and their liquid portion conveys better and quicker bioavailability of the therapeutic agent. Soft Gel and Davidson et al., as previously discussed, disclose that coQ 10 may be formulated as a soft gel capsule.

Also, as discussed previously, the motivation to dissolve coQ 10 in limonene is provided by Erwin, and it is clear that Soft Gel was not cited for this reason. The motivation to formulate coQ 10 as a soft gel is provided by Soft Gel, and it is clear that Erwin was not cited for this reason. Given the teachings of Erwin and Soft Gel and the level of knowledge and skill of one of ordinary skill in the art at the time that the invention was made, it would have been obvious to one of ordinary skill in the art of preparing nutraceuticals to formulate the coQ 10-containing limonene solution of Erwin as a soft gel.

In view of the foregoing, the rejection of record is maintained.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-09-07

Rosanne Kosson

JON WEBER
SUPERVISORY PATENT EXAMINER